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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,245	10/19/2000	Harry F. Prest	10003375-1	6797

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AGILENT TECHNOLOGIES, INC.  
INTELLECTUAL PROPERTY ADMINISTRATION, LEGAL DEPT.  
P.O. BOX 7599  
M/S DL429  
LOVELAND, CO 80537-0599

EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/26/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/692,245

Applicant(s)

PREST

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

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1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenfeld.

Rosenfeld teaches a method of analyzing prostaglandin E2 (PGE2) using PFBBr and PFBHOX derivatizing agents in situ on a column. Samples are then subjected to gas chromatography and electron capture and the trace shown in Figure 8. Two peaks are labeled PGE2, indicating that two derivatives are present. It is the examiner's position that the X-axis on the chromatographic trace is time because the beginning and

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end of the axis are labeled "start" and "stop" which indicate reference to time. See Example 16. Rosenfeld additionally teaches separation of derivatives of THC formed metabolically and further derivatized in situ (Figures 4A-4B).

5. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenfeld.

6. Rosenfeld additionally teaches that Mass Spec analysis can be used in place of Electron Capture (EC) in the PGE2 analysis (col. 19, lines 25-26) and that MS typically includes negative ion chemical ionization mode (col. 1, lines 25-30).

7. Rosenfeld fails to explicitly teach determining retention times, ionizing derivatized analytes or mass spec using negative chemical ionization for the PGE2 or THC analyses.

8. With respect to the alternative rejection, if it is applicant's position that Rosenfeld does not determine retention times, it would have been obvious to determine retention times in order to identify peaks as shown in the Figures and as was known in the art. It would have been obvious to ionize the derivatized analytes in order to perform EC, Mass Spec or Mass Spec with negative ion chemical ionization mode in order to perform the analyses taught or suggested by Rosenfeld for detecting and quantifying the derivatized analytes. It is the examiner's position that prostaglandin constitutes a drug of abuse because it is a hormone-like substance that may be used improperly. With respect to specific drugs of abuse other than THC and prostaglandin, and derivatizing agents other than those disclosed by Rosenfeld, Rosenfeld teaches that the method is widely applicable to drug, herbicide and pesticide residues (col. 7, lines 28-

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32) and it would have been obvious to perform the method on the claimed classes of compounds as known drugs, using known classes of derivatizing agents.

9. Applicant's arguments filed December 18, 2002 have been fully considered but they are not persuasive.

10. Applicant argues that Rosenfeld derivatizes two different isomers of PGE2 to form the two isomeric derivatives in Fig. 8. This argument is not persuasive because Rosenfeld teaches converting PGE2 (a pure analyte (singular)—col. 19, line 68) to derivatives (plural—col. 19, line 19 and Fig. 8). Further, the PGE2 is taken from a mammalian sample, and the naturally occurring form of PGE2 found in mammals is an optically pure (single) isomer. See, e.g., Bundy et al, col. 2, lines 62-66 and Bollinger, col. 3, lines 15-18. It is therefore the examiner's position that a single analyte is derivatized using two different derivatizing agents to form two different (albeit isomeric) derivatives.

11. Applicant argues that Rosenfeld teaches single derivatives of different analytes used in detecting a drug in a sample (marijuana's active agent THC). However, claims 1 and 7 merely require separating two different derivatives of an analyte and do not specify how those derivatives are formed. Delta-9-THC-PFB and delta-9-11-OH-THC-PFB-TMS are both derivatives of THC. Claims 13 and 19 require adding two different derivatizing agents to a sample, and two different agents are added (TMS and PFB) to form derivatives of the analyte (which the examiner has interpreted to be the drug, e.g., THC) to form derivatives of the analyte/drug. Such derivatives are formed, e.g., delta-9-THC-PFB and delta-9-11-OH-THC-PFB-TMS, both of which are derivatives of THC.

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12. The claims as written do not clearly define over the methods of Rosenfeld.
13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

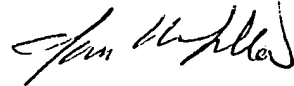
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

A handwritten signature in black ink, appearing to read "Jan M. Ludlow".

Jan M. Ludlow  
Primary Examiner  
Art Unit 1743

jml  
February 22, 2003